# In the United States Court of Federal Claims Office of special masters No. 24-01479

KRISTEN MCLAUGHLIN,

Chief Special Master Corcoran

Petitioner,

٧.

Filed: June 12, 2025

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

John Beaulieu, Siri & Glimstad LLP, Louisville, KY, for Petitioner.

Margaret Armstrong, U.S. Department of Justice, Washington, DC, for Respondent.

### FINDINGS OF FACT AND CONCLUSIONS OF LAW<sup>1</sup>

On January 30, 2024, Kristen McLaughlin filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") resulting from an influenza ("flu") vaccine received on November 13, 2021. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

Respondent has filed his report asserting that Petitioner cannot establish a Table SIRVA because she experienced pain outside her left shoulder (ECF No. 25). After a

<sup>&</sup>lt;sup>1</sup> Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Fact Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

review of the record, I find that Petitioner's symptoms were likely primarily in, and originated from, her shoulder.

## I. Relevant Factual History

Petitioner received the vaccine alleged as causal in her left deltoid on November 13, 2021. Ex. 2 at 1. Five days later (November 18, 2021), she was seen at occupational health, complaining of left shoulder pain that she rated as seven out of ten from a vaccine received at work "a week ago." Ex. 4 at 2. She described pain "on the left shoulder lateral, radiating to the hand," that was exacerbated by abduction. *Id.* Petitioner was advised to see her primary care physician, and given a list of free or low-cost clinics, but it does not appear that any treatment was provided. *Id.* 

About two weeks later (December 4, 2021), Petitioner was seen at a walk-in clinic, complaining of left shoulder pain for the past three weeks after a flu vaccine was administered too high. Ex. 5 at 3. On examination, her left shoulder exhibited decreased range of motion ("ROM") in abduction due to pain. *Id.* She was assessed with left shoulder bursitis and muscle spasm of her left trapezius, and given a muscle relaxant medication and ibuprofen.

About a month after vaccination (December 15, 2021), Petitioner saw Dr. Kayvon Yadidi for a worker's compensation evaluation. Ex. 7 at 3. Her injury was listed as having occurred on November 13, 2021 – the date of vaccination – with Petitioner explaining that she "was administered the flu vaccine at work and shortly after began to experience severe pain from it." *Id.* She rated her pain three out of ten, and stated that it began on November 13th. *Id.* at 4. She. *Id.* 

On examination, Dr. Yadidi recorded Petitioner's left shoulder ROM as 45 degrees in forward flexion (normal: 180 degrees), 30 degrees in extension (normal: 60 degrees), 45 degrees in abduction (normal: 180 degrees), 15 degrees in adduction (normal: 45 degrees), and 30 degrees in external rotation (normal: 90 degrees); all of which were painful. Ex. 7 at 4. She had positive results on the Hawkin's and O'Brien's tests. *Id.* She was diagnosed with left shoulder pain and transient synovitis in her left shoulder. *Id.* at 5. Physical therapy ("PT") was recommended. *Id.* Petitioner attended PT from December 2021 to February 2022. *Id.* 

Petitioner returned to Dr. Yadidi on January 7, 2022. Ex. 7 at 17. She was feeling better but still experiencing "significant pain." *Id.* She was assessed with left shoulder pain, left shoulder transient synovitis, and left shoulder strain, and given oral steroid medication. *Id.* at 18. Dr. Yadidi also recommended continued PT. *Id* 

Two weeks later (January 21, 2022), Petitioner followed up with Dr. Yadidi. Ex. 7 at 47. She had intermittent pain that she rated seven out of ten, and estimated that she

was about ten percent improved. *Id.* Her ROM had improved, now 160 degrees in forward flexion, 45 degrees in extension, 130 degrees in abduction, 60 degrees in internal rotation, and 45 degrees in external rotation, all still painful. *Id.* at 48. She continued to exhibit positive results on the Hawkin's impingement test, but now had negative results on the O'Brien's test. *Id.* She was noted to be "slowly improving," but still had moderate pain at the vaccination site. *Id.* Dr. Yadidi recommended continued PT as well as an MRI to rule out a bursal injury. *Id.* 

Petitioner's shoulder MRI revealed no evidence of a labral, biceps tendon, or high-grade or full thickness rotator cuff tear. Ex. 8 at 21-22. However, there was bone marrow edema at the posterolateral humeral head with overlying infraspinatus tendinosis/insertional fraying and mild soft tissue swelling. *Id.* The radiologist suggested possible SIRVA given Petitioner's history of pain following a recent vaccine. *Id.* 

Petitioner returned to Dr. Yadidi on February 18, 2022, now reporting frequent pain. Ex. 7 at 86-87. Dr. Yadidi noted that she continued to have pain and restricted ROM, and recommended an orthopedic consultation and continued PT. Two weeks later (March 4, 2022), Petitioner reported frequent pain that she rated five out of ten. *Id.* at 103-04. Dr. Yadidi noted that her MRI indicated SIRVA, and resubmitted authorization requests for an orthopedic consult and continuation of PT. *Id.* 

On April 29, 2022, Petitioner followed up with Dr. Yadidi, stating that she saw an orthopedist, who recommended a cortisone injection. Ex. 7 at 147. Petitioner declined the cortisone injection, continuing with anti-inflammatory medication and Tylenol along with PT and cold compression as suggested by the orthopedist. *Id.* Petitioner continued to follow up with Dr. Yadidi and attend PT over the next few months.

On August 18, 2022 (now nine months after vaccination), Petitioner underwent an occupational injury evaluation. Ex. 3 at 11-14. Petitioner stated at this time that she had received a flu vaccine at work in November of the prior year, and had experienced left shoulder pain ever since. *Id.* at 11. She rated her pain five out of ten at rest, increasing to between six and seven with movement, and noted that the pain radiated down to her left biceps. *Id.* at 12. On examination, her left shoulder ROM in flexion and external rotation were reduced compared to her right shoulder. *Id.* at 13. She was diagnosed with SIRVA and chronic left shoulder pain. *Id.* at 14.

Two weeks later (September 1, 2022), Petitioner saw Dr. Emmet Berg for her left shoulder pain. Ex. 9 at 12-14. She had done 18 sessions of PT, with some benefit in ROM but no reduction in pain. *Id.* at 13. Dr. Samson, an orthopedist, had recommended a cortisone injection, which Petitioner declined. *Id.* Petitioner asked for a referral for a second opinion. *Id.* She rated her pain five out of ten at rest and seven out of ten with movement. *Id.* The pain radiated down to her left biceps, and was now associated with "episodic tingling down her arm." *Id.* She was referred to an orthopedic shoulder specialist, Dr. Getelman. *Id.* at 15. Petitioner saw Dr. Getelman the following month

(October 4, 2022), and continued to follow up with him over the next several months, ultimately undergoing shoulder surgery in 2023. Exs. 9, 11. She also attended more PT both before and after surgery. Ex. 11.

#### II. Respondent's Rule 4(c) Report

Respondent argues that Petitioner cannot prevail on a Table SIRVA claim because she experienced pain outside of her left shoulder, and thus cannot satisfy the third QAI criterion. Respondent's Rule 4 Report at \*8. Petitioner reported radiating pain from her shoulder to her hand on November 18, 2021 (Ex. 4 at 2-3); radiating pain down her biceps on August 18, 2022 (Ex. 3 at 12); and radiating pain and episodic tingling on September 1, 2022 (Ex. 9 at 13).<sup>3</sup> Respondent's Report does not discuss the remaining SIRVA QAI or statutory requirements.

#### III. Legal Standards

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the

<sup>&</sup>lt;sup>3</sup> Respondent also requests that Petitioner file missing orthopedic records and any updated medical records. Respondent's Report at \*4 n.3, \*7 n.6.

patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

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Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

## **Analysis**

The record preponderantly supports a finding that Petitioner's symptoms were limited to her left shoulder. Unquestionably, on a few occasions Petitioner reported *some* tingling and pain radiating to her arm and hand. But overall, her symptoms *primarily* occurred in, and originated from, her vaccinated shoulder. *See Valdez v. Sec'y of Health & Human Servs.*, No. 21-0394V, 2024 WL 1526536, at \*6-7 (Fed. Cl. Spec. Mstr. Feb. 28, 2024) (finding third QAI satisfied despite pain radiating to upper arm and forearm because the petitioner *primarily* experienced a shoulder injury consistent with SIRVA); *Cross v. Sec'y of Health & Human Servs.*, No. 19-1958V, 2023 WL 120783, at \*7 (Fed. Cl. Spec. Mstr. Dec. 2, 2022) ("claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain

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extending to adjacent parts of the body, since the essence of the claim is that a vaccine administered *to* the shoulder *primarily* caused pain there") (emphasis in original). In the context of Petitioner's treatment course, with PT and medical visits largely oriented toward the treatment of her shoulder pain, these scattered references to symptoms radiating down her arm are not sufficient to establish that the third QAI is not satisfied. (At best, such instances might limit damages – for example, treatment that was aimed at alleviating *non-shoulder* pain – although it is not immediately evident from this record that this was an issue).

Respondent did not raise any concerns relating to the remaining QAI or statutory requirements, and the record appears to support that these are met. Furthermore, Vaccine Rule 4(c) requires that Respondent's Report set forth "a full and complete statement of its position as to why an award should or should not be granted," and states that it "must contain respondent's medical analysis of petitioner's claims and must present any legal arguments that respondent may have in opposition to the petition." As such, it appears that Respondent agrees that the remaining SIRVA QAI and all statutory requirements are satisfied. However, because Respondent did not specifically address these matters in his report, I will afford him an opportunity to confirm his position in this case in light of my ruling herein. In the meantime, the parties are encouraged to resume informal negotiations, and Petitioner should file the records noted in Respondent's report. Accordingly:

- Petitioner shall file, by no later than <u>Wednesday</u>, <u>July 23</u>, <u>2025</u>, the following:
  - A status report providing an update on the parties' discussions;
  - The orthopedic records of Dr. Samson referred to in Ex. 3 at 14;
     and
  - Any updated medical records.
- Respondent shall file, by <u>Wednesday</u>, <u>August 06, 2025</u>, a status report stating how he intends to proceed in this case in light of this fact ruling.

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master